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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,667	11/14/2003	David J. Cosman	3160-C	5245

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,667	COSMAN ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-16 and 18-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16 and 18-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 21 June 2006 has been entered in full. Claim 17 was cancelled. Claims 13-16, 18-28 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement(s)(IDS) filed 21 June 2006 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections-35 U.S.C. § 112, First Paragraph, Scope of Enablement

Claims 13-16, 18-28 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

an isolated polypeptide having HPR2 polypeptide activity comprising an amino acid sequence comprising SEQ ID NO:21,

does not reasonably provide enablement for:

an isolated polypeptide having HPR2 polypeptide activity comprising an amino acid sequence comprising fragments, mutants and variants of SEQ ID NO:21.

The basis for this rejection is set forth at pages 2-5 of the previous Office Action (28 April 2006).

Applicant states that the claims have been amended rendering the rejections moot. Applicant states that claim 13 and dependent claims, as amended, is directed to an isolated polypeptide having HPR2 polypeptide activity comprising amino acids 24-318 of SEQ ID NO:21. Applicant argues that the specification describes how to make and use several embodiments of the pending claims, including but not limited to HPR2, HPR2-ex9 and HPR2-ex8-ex9. Applicant argues that the pending clams satisfy the enablement and written description standards of 35 U.S.C. 112, first paragraph.

Applicant's arguments have been fully considered but are not deemed persuasive. The specification teaches SEQ ID NO:21 as a human hematopoietin receptor polypeptide (HPR2) (page 1, lines 12-15 and page 78). SEQ ID NO:21 comprises amino acid residues 1-629. The specification teaches SEQ ID NO:23 and SEQ ID NO:25 as splice variants of SEQ ID NO:21. SEQ ID NO:23 comprises 523 amino acids and SEQ ID NO:25 comprises 356 amino acids. The specification teaches that SEQ ID NO:23 is identical to HPR2 from amino acids 1-318 and that SEQ ID NO:25 is identical to HPR2 from amino acids 1-348 (page 14, lines 30-42). The specification however fails to demonstrate a biological activity for SEQ ID NO:23, SEQ ID NO:25 or various fragments of SEQ ID NO:21. The specification discloses that typical biological activities or functions associated with HPR2 polypeptides include intracellular signaling activity, cell proliferation stimulatory activity, cell proliferation inhibitory activity, cell differentiation stimulatory activity and cell differentiation inhibitory activity (page 18, lines 7-15). The skill in the hematopoietic receptor art is not high because there are a several classes of receptors with great diversity of function. The Examiner cited references in

the last Office Action, which teach that many members of the hematopoietin receptor family are expressed differently and transduce diverse signals. Thus, even for a family of hematopoietic receptors, the biological activities may vary broadly. There are no working examples of polypeptides less than 100% identical to the polypeptide comprising SEQ ID NO:21, thus the skilled artisan would not know how to use non-identical polypeptides on the basis of the teachings in the specification unless they possessed some sort of function, which the specification fails to teach. Without sufficient guidance regarding a distinguishing biological function of HPR2, the changes which can be made in the structure and still maintain sufficient activity is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Rejections-35 U.S.C. § 112, First Paragraph, Written Description

Claims 13-16, 18-28 remain rejected under 35 U.S.C. 112, first paragraph, written description. The basis for this rejection is set forth at pages 5-7 of the previous Office Action (28 April 2006).

Applicant incorporates their response to the rejection under 35 U.S.C. 112, first paragraph, enablement in response to the rejection under 35 U.S.C. 112, first paragraph, written description. Applicants arguments have been fully considered but are not found to persuasive for reasons of record and the reasons discussed above in the maintained 35 U.S.C. 112, first paragraph, enablement rejection. The instant claims

do not require that the polypeptide possess any particular biological activity or any other distinguishing feature. The specification, does not provide any guidance as to what changes should be made and which regions of the instant protein are functionally critical. There is no description of variants of SEQ ID NO:21 that exist, while still maintaining function. In the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RMD
8/24/06

Marianne P. Allen

8/25/06

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